

## **REMARKS**

Claims 34 through 44 are pending in the application. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

## **REJECTION UNDER 35 U.S.C. § 102**

Claims 34-37 and 39 stand rejected under 35 U.S.C. § 102(a) as being anticipated by Ueda (U.S. Patent No. 5,681,260). This rejection is respectfully traversed.

### **Claims 34, 35 and 39**

With respect to claims 34, 35 and 39, these claims clarify that the externally applied magnetic field causes the magnet members located on the distal end of the catheter ***to align*** relative to the direction of an externally applied magnetic field.

The Office Action alleges on page 2 that Ueda discloses a catheter device having magnetic members (19/82/20/95) that align relative to the direction of an externally applied magnetic field applied from magnetic generator (11/31/61). However, Ueda discloses a tip that is **attracted by a magnetic force**, which is ***moved towards*** the magnetic force generating part 31. (Ueda, column 9, lines 14-28).

The Applicant notes that a magnetic tip **attracted towards an external magnet** *is not the same* as a magnetic tip **aligning with** the direction of a magnetic field. For example, a magnet held close above a compass causes the compass needle to be attracted up towards the magnet, which is very different from a magnet rotated above a compass that causes the compass needle to rotate and align with the direction of the magnetic field of the rotating magnet. The Applicants also note that a magnetic tip can be aligned by a magnetic field in directions **other than** towards the magnet.

Ueda discloses a magnetic tip that is attracted towards a magnet rather, not a magnetic tip that aligns with the direction of a magnetic field of the magnet. Ueda discloses that “when the endoscope 2 is pushed into a large intestine and then an electric current is passed to the magnetic force generating part 31 made of an electro magnet, a magnetic force acting between this magnetic force generating part 31 and tip part body 19 (or hood 21) will be generated.” (Ueda, column 9, lines 14-28). Ueda further discloses that if the horizontal position of the magnetic force generating part 31 is sequentially moved along the bent tube cavity of the large intestine 41 as shown by the dotted lines 31a, 31b, 31c and 31d, the tip part body 19 (or the hood 20) **will be attracted by the magnetic force**, and will be therefore **be moved to trace the moving course of the magnetic force generating part 31** so that the tip part 89 may be inserted in the deep side of the large intestine 41. (Ueda, column 9, line 21-27). The tip part 8a will be advanced **while being attracted** by the magnetic force by the magnetic force generating part 31 from below the patient. (Ueda, column 9, line 27-30).

Ueda also discloses another embodiment in which the “operator inserts the endoscope 42 into the large intestine 41 through the anus by a pushing operation. Then, the magnetic force generating parts 66A and 66B of the magnetic force generating apparatus 61 are driven and the tip part 8a of the endoscope is attracted the same as in the first embodiment by the magnetic forces and is inserted into the deep side of the large intestine 41.” (Ueda, column 11, line 9-27). To “further insert the tip part 8a of the endoscope into the deep side, the annular magnetic force generating apparatus 61 is moved, and the magnetic force of the magnetic force generating part 66A is elevated. Then, the permanent magnet or ferromagnetic substance part of the

endoscope **tip part will be strongly attracted and moved towards the magnetic force generating part 66A** ... as shown in FIG. 9(B). (Ueda, column 11, lines 9-35). Thus, Ueda teaches controlling the movement of the magnetic force generating parts 66A and 66B, and further the strength of the magnetic force, **to attract the endoscope towards the magnet force generating parts.**

Contrary to Ueda, the devices in claims 34, 35 and 39 are not attracted towards a magnetic force generating source, but rather are aligned in the direction of a magnetic field. An externally applied magnetic field causes the magnet members located on the distal end portion **to align** relative to the direction of an externally applied magnetic field, whereby the distal end is oriented by changing the direction of the externally applied magnetic field to cause the magnet members to align relative to the magnetic field. (paragraphs 63-64 of the present published application 20020019644). Thus, unlike Ueda, the claimed magnet members may be **aligned** in a desired direction other than towards the magnet by changing the magnetic field's direction. (See field lines generated by a magnetic navigation system as shown in Fig. 2-6 of commonly assigned U.S. Pat. No. 6,702,804).

Furthermore, there is no indication that the Ueda device would inherently be capable of aligning with a magnetic field direction as in the present claims. The mere fact that a certain thing could result from a given set of circumstances is not sufficient to support the determination that the certain thing is possible. In re Oelrich, 212 U.S.P.Q. 323, 326 (CCPA 1981). When relying on the theory of inherency, an examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the

teachings of the applied art. Ex parte Levy, 17 U.S.P.Q. 1461, 1464 (Bd. Patent App. & Int. 1990). Here, inherency does not flow with the teachings of Ueda, which solely teaches attraction of a magnet tip towards a magnetic force generating part. In fact, there is every indication that the Ueda device would not be capable of being aligned in directions other than towards the magnet source, because the Ueda device is specifically intended to be attracted towards a magnetic force generating source. It is well known that a magnet's responsiveness relative to distance falls off with the fourth power, so employing magnetic force generating sources for attracting a magnet tip towards the magnetic force generating source would require high field strength. Here, Ueda discloses that the magnetic force of the magnetic force generating part 66A is elevated to attract the tip part. Thus, Ueda teaches a magnetic tip part that is intended to be **attracted towards** a magnetic force generating source, which **precludes aligning the tip in directions other than towards** the magnetic force generating source.

Accordingly, the Applicants submit the atherectomy devices in claims 34, 35 and 39 that are capable of aligning relative to a magnetic field are not anticipated by Ueda, and are not inherent in the Ueda device. The whole point of the teachings of Ueda is to attract a tip towards a magnetic force generating source. Any attraction or movement of a magnetic tip towards a magnet source would interfere with aligning the magnetic tip with the direction of a magnetic field. Thus, the presently claimed magnet members that cause the tip to be oriented or aligned by a magnetic field distinguish claims 34, 35 and 39 from Ueda. As such, the Applicant submits that claims 34, 35 and 39 are allowable for at least these reasons.

### **REJECTION UNDER 35 U.S.C. § 103**

Claims 38, 40-43 stand rejected under 35 U.S.C. § 102(a) as being unpatentable over Ueda (U.S. Patent No. 5,681,260). This rejection is respectfully traversed.

With respect to claims 36-38 and 40-43, these claims ultimately depend from claims 35, 36 or 39, which Applicants believe to be distinguished over Ueda for the reasons stated above. Thus, Applicants submit that claims 36-38 and 40-43 are also patentable by virtue of their dependence from the above independent claims.

The Applicants further submit that it would not have been obvious in view of Ueda to include magnet members that align relative to a magnetic field direction, because Ueda only teaches attraction towards a magnetic force generating source. As such, Applicants believe that claims 34, 35 and 39 are not obvious in view of Ueda.

### **DOUBLE PATENTING REJECTION**

Claims 34-42 are rejected under the non-statutory double patenting doctrine over claims 1-26 of US Patent 5,681,260. This rejection is respectfully traversed.

With regard to the double patenting rejection of claims 34-42, the Applicants submits that none of the claims in the Ueda patent read on the claims of the instant application, regarding the distal end being oriented by changing the direction of the externally applied magnetic field to cause the magnet members to align relative to the magnetic field. Thus, the Applicants submit claims 34-43 are patentably distinct.

### **NEW CLAIMS**


The Applicant has added claims 43 and 44 to claim variations in the features of the optical conduit as disclosed in paragraphs 86 and 88 of the present published application 20020019644.

### **CONCLUSION**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot by the present amendments. The Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If it will advance the prosecution of this application, the examiner is invited to call the undersigned at (314) 726-7500.

Respectfully submitted,

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